ADE
Waagen fürs Leben.

Blood pressure monitor

with Bluetooth and data management in linked app

Operating Instructions

BPM 1401
adeVital
Pressure

Subject to technical changes as a result of product improvements.
Operating Manual_BPM1401_EN_131210_REV001

Thank you for purchasing this *Blood Pressure Monitor with app* from the adeVital product range.
All the products in the innovative *adeVital range – body analyser scales, blood pressure monitor and activity meter* – have Bluetooth functionality to transfer data to the adeVital app. The straightforward interface of the free-to-download app allows you to check your progress easily and clearly and ensures your health data is always available and up-to-date.

Table of Contents

SAFETY INFORMATION AND OPERATING INSTRUCTIONS

SAFETY INFORMATION

The warning signs and symbols are important to ensure you use this product correctly and safely and to prevent injuring yourself or others. The warning signs and symbols on the product and in these operating instructions have the following meanings:

Symbol for “Read the operating instructions!”

Symbol for a Bluetooth-enabled device

Symbol for “Type BF applied part” (medical equipment classification)

Symbol for “Serial Number”

Symbol for “Direct Current”

Symbol for “Manufacturer”

Only for indoor use

T1A/250V Φ 3.6*10CCC

Symbol for “Protection Class II device”

Symbol for “Meets the requirements of European Directives”

Symbol for “Recycling” – Electrical products must not be disposed of with normal household waste. Please recycle the device. Please contact your local recycling centre or retailer for tips on recycling.

ATTENTION!

Please read these operating instructions carefully before using the device.

This device is only intended to be used by ADULTS AT HOME.

This device is not designed for non-invasive measurement and monitoring of arterial blood pressure. It is not designed for use at extremities other than the upper arm or for functions other than measuring blood pressure.

Do not confuse self-monitoring with self-diagnosis. You can use this device to monitor your blood pressure. Start or stop medical treatment only after consulting your doctor. If you are taking medication, discuss with your doctor what would be a suitable time to measure your blood pressure. Never change your prescribed medication without your doctor's agreement.

This device is not suitable for continuously monitoring blood pressure in medical emergencies or operations.

If the pressure in the sleeve exceeds 40 kPa (300 mmHg), the sleeve deflates automatically. If the sleeve does not deflate when your blood pressure exceeds 40 kPa (300 mmHg), remove the sleeve from your upper arm and press the button to stop it inflating.

Do not use the blood pressure monitor near to strong electromagnetic fields (E.G. MOBILE TELEPHONE), particular if using the adapter.

Do not touch the adapter and the patient at the same time.

The blood pressure monitor is not approved as a category AP or APG device. It is not suitable for use in the presence of a flammable anaesthetic mixture with air (or oxygen and nitrous oxide).

PLEASE KEEP THE DEVICE OUT OF REACH OF CHILDREN, AS INHALING OR SWALLOWING SMALL PARTS MAY CAUSE INJURY OR EVEN DEATH.

Please use the ACCESSORIES and attachments recommended and approved by the MANUFACTURER. If you do not, you may damage the device and may put the user/patient at risk.

PLEASE ENSURE THAT THE BLOOD PRESSURE MONITOR IS FUNCTIONING CORRECTLY AND IS IN GOOD WORKING CONDITION BEFORE USE.

INSTRUCTIONS FOR USE

– The *ADE adeVital Pressure BPM1401 Blood Pressure Monitor with app* allows you to measure your blood pressure and pulse and to save your measurements automatically. The blood pressure monitor has a life of at least 3 years.

– The measurements provided by the BPM1401 have the save value as results provided by a trained medical specialist using a sleeve and stethoscope.

– These operating instructions contain important information about safety and how to care for your device and provide step-by-step instructions on how to use the product.

– Please read the full operating instructions carefully before using the product.

FEATURES AND COMPONENTS

FEATURES

– User device memory for 60 x 1 measurements/management of all measurement results is unlimited in the app

– Reliable and rapid data transfer to the adeVital app via Bluetooth

– Accurate measurement of blood pressure data (systolic and diastolic values) on the upper arm

– Measurement of pulse frequency

– Heartbeat irregularity indicator (arrhythmia warning)

– Measurement while inflating

– Oscillometric method, i.e. measuring the pulse oscillations of the blood flow

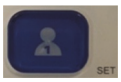
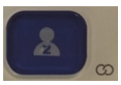
– Classification of measured values as using preset values from the World Health Organization (WHO)*

– Date and time display

– Auto switchoff

– Battery level indicator

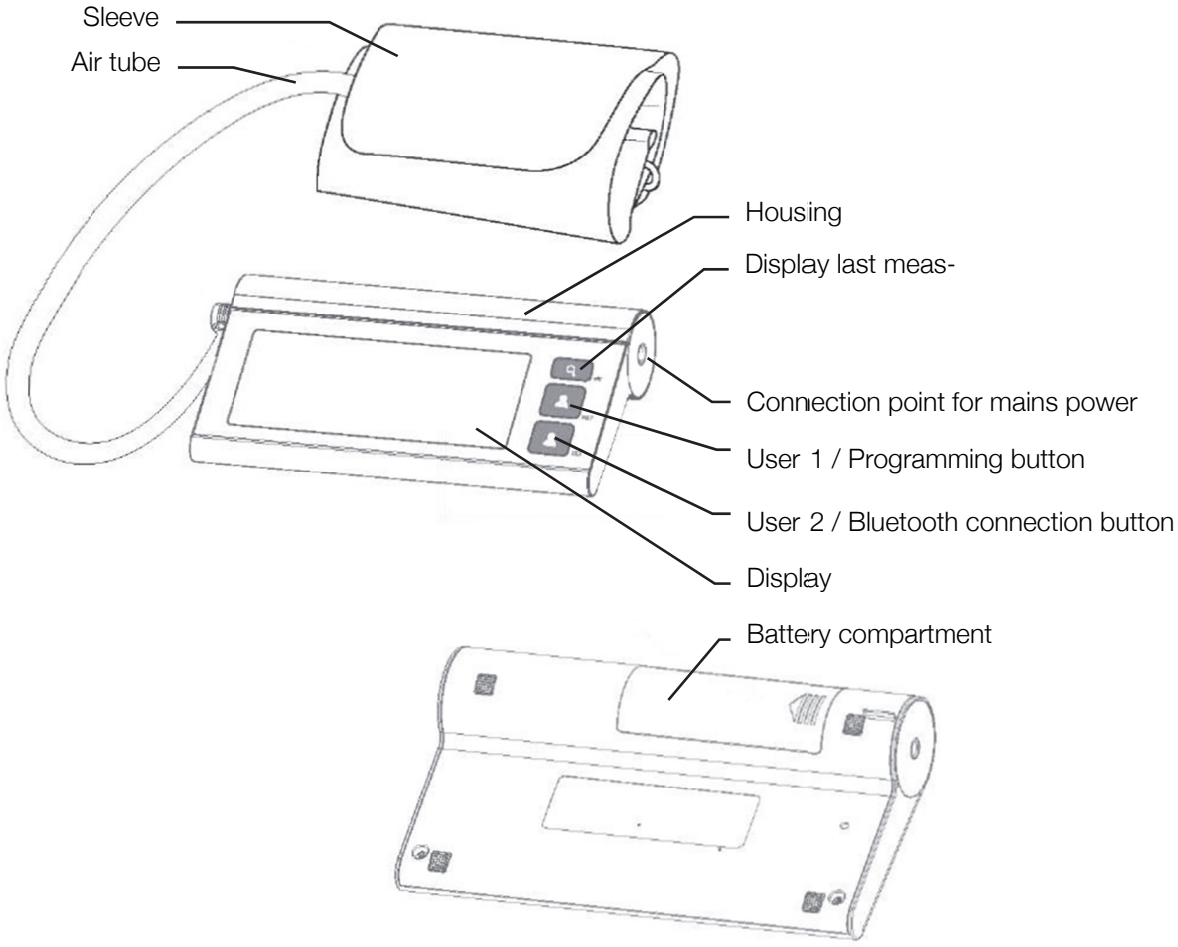
THE LCD DISPLAY

SYMBOL	DESCRIPTION	EXPLANATION
	Retrieve data/setup button	Access saved measurements Setup button to adjust the time
	User 1	Start measurement for user 1 and automatically transfer the results Programming button
	User 2	Start measurement for user 2 and automatically transfer the results Button to connect to the app
SYS	Systolic blood pressure	Top blood pressure value
DIA	Diastolic blood pressure	Bottom blood pressure value
Pul/min	Pulse	Pulse beats/minute
	Pulse detection	Shows your heartbeat when it is detected
	Data ready for transfer	Measurement data has been saved on the device
	Data transfer	Data transfer in progress
AVG	Average	Average of the last three measurements
	Impact reminder	Knocks and shocks cause inaccurate measurements
	Low battery	The batteries are weak and must be replaced
mmHg kPa	Unit	Blood pressure unit of measurement
AM 88/88	Current time	Month, day (hour, minute)
	Deflation	The sleeve is deflating
	Irregular heartbeat	Please read the further information on page 16
	Bluetooth connection	Connects the BPM1401 to the active app

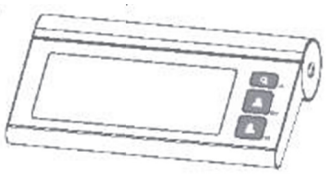
BLOOD PRESSURE MONITOR COMPONENTS

The following components are parts of the device or are already built into the device:

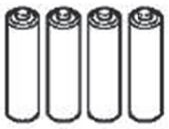
- Soft sleeve: 22 – 32 cm
- BPM1401, housing made from ABS plastic
- Repeater
- Air tube
- Pump
- Valve
- 128 mm x 50 mm blue LCD display with white background light
- Connection point for the mains adapter
- Battery compartment



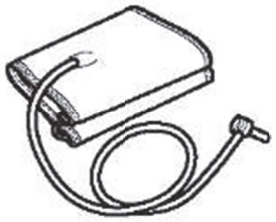
CONTENTS OF THE PACKAGE



– BPM1401 blood pressure monitor



– 4x AAA 1.5 V alkali batteries



– Sleeve (type BF applied part) (AC2232-02)

– Instructions

FIRST USE

Remove all the components from the packaging and remove the protective film from the components.

Keep the packaging for storage and to return the product, if necessary.

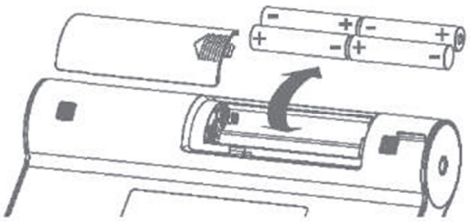
This device *must not* be used by individuals (including children) with limited physical, sensory or mental abilities, or who are lacking necessary experience and understanding, unless they are supervised by another individual responsible for their safety or have been instructed in the use of the device. It should be ensured that children do not play with the device.

HOW TO INSTALL THE BATTERIES

– Open the battery compartment cover on the back of the BPM1401.

– Place the batteries (4 x 1.5 V AAA) into the battery compartment observing the polarity markings.

– Close the battery compartment cover.



ATTENTION!

REPLACE THE BATTERIES UNDER THE FOLLOWING CIRCUMSTANCES:

is displayed on the LCD display.

– The LCD display becomes weaker.
– The LCD display does not light up when you switch on the blood pressure monitor.
– Used batteries should be disposed of as hazardous waste. Do NOT dispose of them as normal waste. Please observe local regulations and recycling information when disposing of used batteries.

Battery life: Approx. 44 days

Battery capacity: 600 mAH. At a rate of three blood pressure measurements per day, 35 s per measurement, 20 s to display the results and 10 s for data transfer. The power consumption is 400 mA for measurements, 50 mA to display measurements and 50 mA (additionally) for data transfer. The switched off device requires 35 µA.

Remove the batteries if the device will not be used for a longer period of time.

Used batteries may leak.

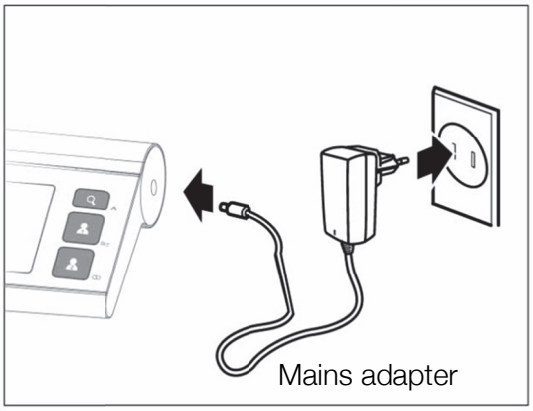
EXTERNAL POWER SUPPLY

100-240 V~, 50-60 Hz, 400 mA (only with mains adapter UE08WCP-060100SPA! / Not provided!)

Disconnect the mains adapter cable from the blood pressure monitor when you want to disconnect it from the mains.

Note:

The connection point for the mains adapter is on the right side of the device. Do not place anything in the way to ensure that the mains adapter cable can be disconnected easily.



INSTALLING THE ADEVITAL APP AND CONNECTING

Mobile or portable devices with Bluetooth functionality as per the BLE Technical Specifications and the Blood Pressure Profile (BLP) protocol from the international Bluetooth SIG organisation can receive your personal data via modern Bluetooth 4.0 technology.

Available on the App Store

The adeVital app is available from the App Store. You can search for the app in the Store and install it on your iPhone.

- Free adeVital app download
- Clear presentation and tracking of all data and values

MONITORING FOR BLUETOOTH MEASUREMENT DEVICES

- Displays the date for all recorded values
- Displays systolic and diastolic reading and pulse rate
- Pulse frequency
- Create line charts for various time intervals
- Graph or table view
- Easy data delivery via the integrated email function, Facebook and Twitter

Simply install our specially developed app and connect your blood pressure monitor to your mobile and portable devices. You will then be able to use the extensive evaluation options in the adeVital app.

The app to connect the blood pressure monitor is only available for iPod touch (5th generation), iPhone 4S, iPhone 5, iPhone 5s, iPad 3, iPad Air, iPad mini and newer versions.
Compatibility with Bluetooth 4.0 is required.

ATTENTION!

BLUETOOTH MODULE NO.:	NRF8001
RADIO-FREQUENCY RANGE:	2402 MHz to 2480 MHz
OUTPUT POWER RANGE:	0 dBm
SUPPLY VOLTAGE:	3.3 V
TRANSMISSION RANGE:	10 m

– Activate Bluetooth and start the app.

Make sure that Bluetooth and the adeVital app are running so that you can connect the devices.

– PRESS AND HOLD THE "USER 2" BUTTON TO START THE LINKING PROCESS.

– The  symbol and  symbol appear alternately on the LCD display and indicate that the linking process is running.

– The  symbol is displayed on the LCD display when the connection is established.

– If the connection fails,  is displayed on the LCD display.

BLOOD PRESSURE MONITOR SETTINGS

Please set the time and date before using the blood pressure monitor for the first time, so that all recorded measurements have a correct timestamp. (defaults: date: 2012-01-01; time: 00:00; unit of measurement: mm Hg)

The blood pressure monitor switches off automatically in setup mode 60 seconds after the last input.

1. When the blood pressure monitor has switched off, press and hold the "User 1" button to set the time and date.

2. The hours and minutes are shown on the display with flashing hour digits.
   Adjust the hour by pressing the button, AM (morning) changes to PM (afternoon) after 12 hours.

3. Press the SET button to switch to minutes and set the minute using the button. Holding down the button fast forwards through the minutes.

4. Repeat steps 2 and 3 to confirm the [MONTH AND DAY].

5. Press the SET button to confirm the [Day] and to switch to year (the year with flash).

6. Hold down the button until the correct year is displayed. The numbers are in a loop so that it returns to [1]. Press the SET button again to confirm the [YEAR] and switch automatically to the UNIT OF MEASUREMENT.

7. Repeat steps 2 and 3 to confirm the [UNIT OF MEASUREMENT].

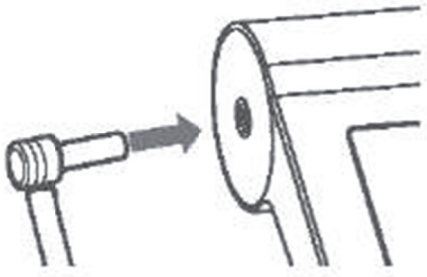
[mmHg]

[kPa]

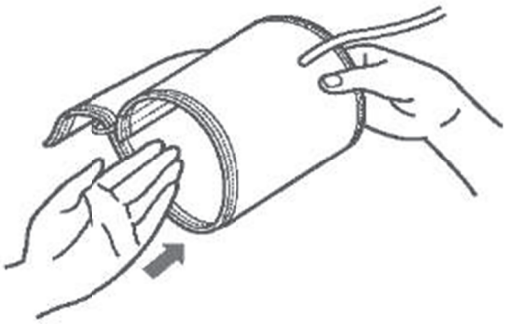
STARTING MEASUREMENT

PUTTING ON THE SLEEVE

1. Connect the air tube connector for the sleeve to the tube connection point on the left side of the blood pressure monitor.

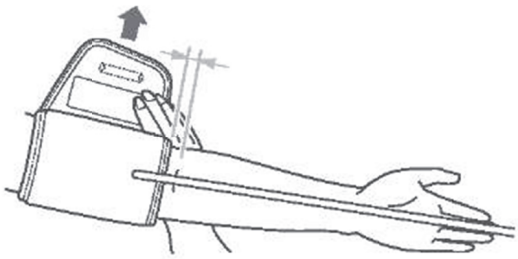


2. Place the sleeve around your upper arm (see picture on right).



3. Fasten the sleeve. Ensure that the sleeve is 2 to 3 cm above your elbow.

   When the sleeve is closed around your upper arm, you should only be able to push one finger between the sleeve and your arm.



4. Correct posture:

   Expose your arm or only wear close-fitting clothing for the measurement.

   Sit comfortably and relaxed on a chair.

   The middle of the sleeve should be at the same level as your heart.

   Your legs should be relaxed and your feet point outwards.

   Your palm should be facing upwards.

STARTING MEASUREMENT

After correctly positioning the sleeve, press the “User 1” (or “User 2”) button to switch on the blood pressure monitor. The measurement is then performed automatically.

1. LCD display

2. Automatic zeroing

3. Automatic inflation and measurement.

4. Displaying and saving results that are transferred automatically to the adeVital data management system. The ((•)) symbol flashes.

5. Press “User 1” (or “User 2”) to switch off the blood pressure monitor. Otherwise, the blood pressure monitor switches off automatically 1 minute after the last action.

A. Once the entire measurement has finished, press another button to start the measurement again with the blood pressure monitor.

B. A maximum of 60 recorded sets of measurement results for user 1 and user 2 can be saved on the device and the number is unlimited in the adeVital app.

ACCESS SAVED MEASUREMENTS

1. Once the blood pressure monitor is switched off, press the “Search” button to open saved measurements. The blood pressure monitor displays the average of the last three measurements.

2. Press the “Search” button again to browse the records. Up to 60 records are saved for each user ID. Measurement date and time and shown alternately.

3. Press the “User 1” or “User 2” button to switch between users.

NO RECORD FOR USER 2

4. Press “User 1” (or “User 2”) to switch off the blood pressure monitor. Otherwise, the blood pressure monitor switches off automatically 1 minute after the last action.

MEASUREMENT TIPS

MEASUREMENTS MAY BE INACCURATE UNDER THE FOLLOWING CIRCUMSTANCES, WHICH SHOULD BE AVOIDED:

Within 1 hour of eating and/or drinking

Measurements straight after tea, coffee or smoking

Within 20 minutes of a bath

If you are talking or moving your finger

In a very cold room

If you need the toilet

DATA TRANSFER

If the BPM1401 and your iPhone have connected successfully, the measurement data is transferred automatically via Bluetooth to your iPhone when the app is open.

The symbol is hidden once the data has been transferred successfully. You can then check your personal health data on your iPhone.

If data transfer fails, the symbol is not hidden. The queued measurement data is temporarily saved on the blood pressure monitor and is transferred to your iPhone after the next measurement.

ATTENTION!

– Interference is possible near to devices with the symbol. The blood pressure monitor may interfere with nearby electrical devices.

– This product must be connected to a Bluetooth device at 2.4 GHz to transfer data.

How can I reduce any possible interference?

1. The distance between the blood pressure monitor and the Bluetooth device should be as low as possible (between 1 m and 10 m). There should be no obstacles blocking the Bluetooth connection between the blood pressure monitor and the Bluetooth device.
2. Other electronic devices (particularly devices with Bluetooth transfer/transmitter) must be kept at least 1 m away from the blood pressure monitor to avoid interference.

ERROR MESSAGES AND TROUBLESHOOTING

This section contains a list of error messages and frequently asked questions for problems that may occur with your blood pressure monitor. If the device is not working as expected, please check this list before you send in the device for repair.

ERROR MESSAGES

Problem	Symptom		Please check	Solution
No power	The display is weak or does not light up.		Batteries are empty.	Install new batteries.
			Batteries are not installed correctly.	Install batteries correctly.
Low battery		on the display	The batteries are weak.	Install new batteries.

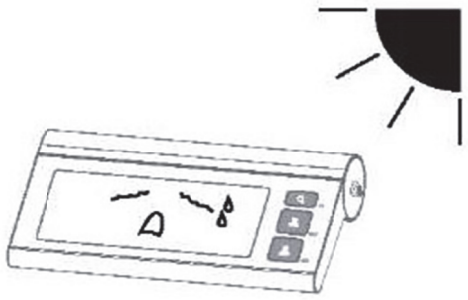
Problem	Symptom	Please check	Solution
Error message	E 1 is displayed	The sleeve is not tight enough.	Refasten the sleeve and repeat the measurement.
	E 2 is displayed	The sleeve is too tight.	Refasten the sleeve and repeat the measurement.
	E 3 is displayed		Relax for a moment and then repeat the measurement.
	E 10 or E 11 is displayed		Movement can affect the measurement. Relax for a moment and then repeat the measurement.
	E 20 or E 21 is displayed		Relax for a moment and then repeat the measurement.
	Eexx is displayed	A calibration error has occurred.	Please repeat the measurement. If the problem persists, please contact your dealer or our customer service. Contact information and instructions for returning your product are provided in the Warranty section.

DURING DATA TRANSFER

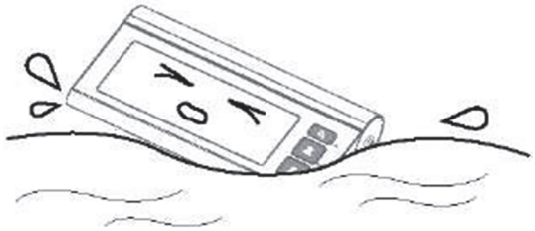
Error	Description	Solution
Data Transfer failed.	Bluetooth is OFF.	Turn Bluetooth ON via “Settings >> General >> Bluetooth”.
	The app is OFF (not running).	Tap the app symbol to start the app.
	Outside the maximum Bluetooth range.	Place your iPhone closer to the device.

DEVICE CARE

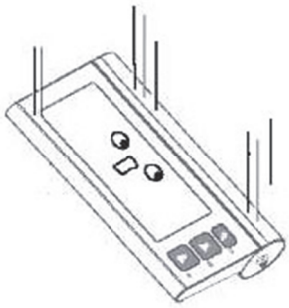
Please follow these instructions to care for your device:



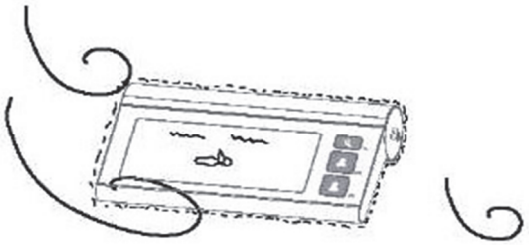
Put the device in a dry place and avoid direct sun-light



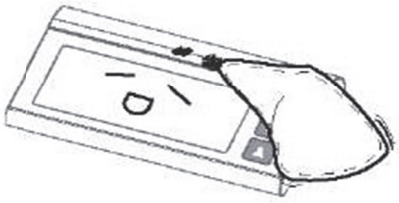
Do not submerge the device in water



Avoid shaking or knocking the device



Avoid exposing the device to dusty environments and variations in temperature



Remove dirt with a lightly dampened cloth

Do not wash the sleeve

Cleaning:

Before use	–	Take the entire device out of its storage bag. Use a soft cloth to remove dirt from the blood pressure monitor. Clean the sleeve with some alcohol before attaching it.
After use	–	Wipe off the device with a soft cloth. Disinfect the sleeve with some alcohol. Place the entire device in the storage bag.

– **PLEASE ALWAYS DISINFECT THE SLEEVE BEFORE YOU USE IT FOR A DIFFERENT PATIENT.**
– Please note that **ONLY THE MANUFACTURER'S SERVICE TECHNICIANS** are permitted to replace parts.

– Old sensors may result in inaccurate measurements. Loose electrodes may prevent the blood pressure monitor switching on.

Proper care has a major influence on the life of your blood pressure monitor.

– Do not use aggressive detergent, abrasives or other chemicals to wipe dirt off the device. This can cause discolouration, malfunction and damage to the device.
– Do not disassemble or modify the device. In the event of problems with the device, please contact service partner.

CE DECLARATION OF CONFORMITY

– This product is manufactured according to harmonised European standards. It complies with the provisions of the following EC Directives:
– EMC Directive 2004/108/EC
– R&TTE Directive 99/5/EC
– MDD Directive 93/42/EEC

WARRANTY

ADE agrees to rectify any material or manufacturing defects by offering free repair or replacement, for a period of 3 years from the purchase date (excluding wearing parts and batteries). At the time of purchase, please get the retailer to fill in and stamp the guarantee card. In case of a warranty claim, please return the blood pressure monitor to your retailer including guarantee card and stating the reason for the claim.

ADE GmbH & Co.
Hammer Steindamm 27 – 29, 22089 Hamburg, Germany

DISPOSAL

LEGAL INFORMATION OBLIGATION REGARDING THE DISPOSAL OF BATTERIES

Do not dispose of batteries in domestic waste. As a consumer, you are legally required to return used batteries. You may return your used batteries to public collection points in your community or to any retailer that sells batteries of the same type.

Note:

The following symbols are used on batteries:
Li = Battery contains lithium
Al = Battery contains alkali
Mn = Battery contains manganese

CR (Li); AA (Al, Mn); AAA (Al, Mn)

DISPOSAL OF OLD ELECTRICAL DEVICES

The symbol on the product or its packaging indicates that this product must not be disposed of with regular household waste; instead, it must be disposed of at a collection point for the recycling of electrical and electronic equipment.
For further details about recycling, contact your local council, municipal recycling companies or the shop where you bought the product.

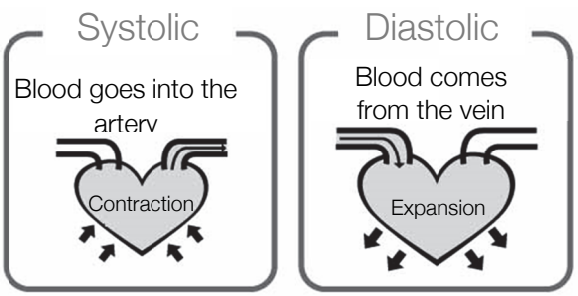
Best regards,

ADE GmbH & Co.

ABOUT BLOOD PRESSURE

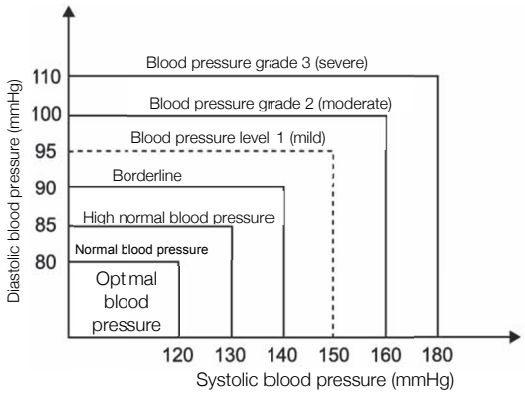
SYSTOLIC/DIASTOLIC BLOOD PRESSURE

Your blood pressure is at its maximum in the cycle when the chambers of the heart contract and pump blood out of the heart. This value is referred to as the systolic pressure. Your blood pressure is at its minimum in the cycle when the chambers of the heart expand. This value is referred to as the diastolic pressure.



STANDARD BLOOD PRESSURE CLASSIFICATION

The blood pressure classification published by the World Health Organization (WHO) and the International Society of Hypertension (ISH) in 1999 is as follows:



ATTENTION!

Only a doctor can tell you what your normal range of blood pressure would be. Please consult a doctor if your blood pressure is outside that range. Please note that only a doctor can tell you whether your blood pressure has reached a dangerous level.

Value / Blood pressure (mmHg)	Optimal	Normal	High normal	Mild	Moderate	Severe
SYS	<120	120-129	130-139	140-159	160-179	•180
DIA	<80	80-84	85-89	90-99	100-109	•110

IRREGULAR HEARTBEAT

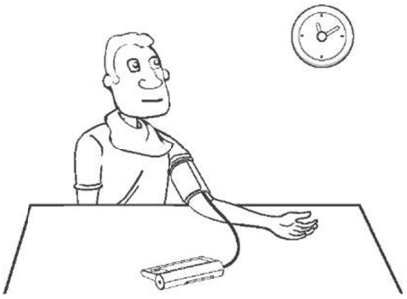
This blood pressure monitor comes with an intelligent irregular heartbeat detector *(IHB)*. The IHB records the intervals between heartbeats during every measurement and determines the standard deviation. If the calculated deviation is greater or equal to 15, the IHB symbol is shown on the display with the result.

ATTENTION!

The IHB symbol indicates that a pulse irregularity in conjunction with an irregular heartbeat has been identified during the measurement. This is normally NOT a cause for concern. However, if the symbol appears frequently, we recommend that you seek medical advice. Please note that the device does not replace proper testing of your cardiovascular system, but can detect pulse irregularities at an early stage.

VARIATIONS IN BLOOD PRESSURE OVER THE COURSE OF A DAY

1. Your blood pressure varies during the day. This depends in part on how tightly you attach your sleeve and the position you adopt for measurement. You should therefore try to measure under the same conditions.
2. Variations in blood pressure are greater if you are taking medication.
3. Wait at least 4-5 minutes before the next measurement.



DIFFERENT BLOOD PRESSURE RESULT AT THE HOSPITAL/FROM THE DOCTOR AND AT HOME

Your blood pressure varies during the day. Reasons can include the weather, emotions, movement etc. and, in particular, the 'white coat' effect in the hospital or at the doctor's, which can cause higher blood pressure results than at home.

IF YOU MEASURE YOUR BLOOD PRESSURE AT HOME ON YOUR OWN, PLEASE NOTE THE FOLLOWING:

– The sleeve must be placed correctly.
– The sleeve must not be too tight or too loose.
– The sleeve must not be attached at the wrist.
– You should not be worried when the sleeve inflates.
– You should breathe in deeply 2-3 times before measurement starts.

Tip: Leave 4-5 minutes before the measurement to calm down.

DIFFERENT BLOOD PRESSURE RESULTS ON EACH ARM

Blood pressure can be measured on both arms, but the results are different on each arm. You should therefore always measure your blood pressure on the same arm.

TECHNICAL DATA

Power supply:

Battery operated:	6 V (4 x AAA alkali batteries)
Mains operated:	100-240 V~, 50-60 Hz,400 mA (only with mains adapter UE08WCP-060100SPA!)

Display mode: Blue LCD with white background lighting
Display area: 128 mm (L) x 50 mm (W)

Measurement mode: Oscillographic test method

Measurement range: Blood pressure: 0-40 kpa (0~300 mmHg)
Pulse: (40-199) pulse beats/minute

Precision:

Blood pressure:	At	5 °C – 40 °C	within ±0.4 kPa (3 mm Hg)
	At	0 °C – 45 °C	within ±0.7 kPa (5 mm Hg); pulse: ±5 %
(or	at	5 °C – 40 °C)	

Operating conditions:

Temperature:	5 °C – 40 °C
Relative humidity:	•85 %
Air pressure:	86 – 106 kPa

Storage & transport conditions:

Temperature:	-20 °C – 60 °C
Relative humidity:	10 % - 93 %
Air pressure:	50 – 106 kPa

Circumference of upper arm that can be measured: Approx. 22 – 32 cm

Weight: Approx. 385 g (without batteries)

External dimensions: Approx. 120 x 160 x 69 mm

Accessories: 4 x AAA alkali batteries, user instructions

Operating mode: Continuous operation

Protection class: Type BF applied part

Device classification: Battery operated: Medical equipment (ME) device with internal power supply via mains adapter: Class II ME device

IP class: IP22

Software version: V01

AVAILABLE ACCESSORIES

Mains adapter

Storage bag

ADAPTER:
Type: UE08WCP-060100SPA
Input: 100-240 V, 50-60 Hz, 400 mA
Output: 6 V ⎓ 1 A
(expected life: 50,000 h)

EMC INFORMATION

MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS (IEC 60601-1-2)		
The BPM1401 blood pressure monitor is intended to be operated in the electromagnetic environment specified below. The customer or the user of the BPM1401 blood pressure monitor should ensure that it is operated in such an environment.		
Radiated emission test	Compliance	Electromagnetic environment (EME) – guidance
Radio-frequency emissions in accordance with CISPR 11	Group 1	The BPM1401 blood pressure monitor uses radio-frequency energy for internal function only. Therefore, its radio-frequency emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Radio-frequency emissions in accordance with CISPR 11	Class B	The BPM1401 blood pressure monitor is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic current emissions in accordance with IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions in accordance with IEC 61000-3-3	Not applicable	

MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY (IEC 60601-1-2)			
The BPM1401 blood pressure monitor is intended to be operated in the electromagnetic environment specified below. The customer or the user of the BPM1401 blood pressure monitor should ensure that it is operated in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment (EME) – guidance
Electrostatic discharge (ESD) in accordance with IEC 61000-4-2	±6 kV contact discharge ±8 kV air discharge	±6 kV contact discharge ±8 kV air discharge	Floor should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst in accordance with IEC 61000-4-4	±2 kV for mains	±2 kV for mains	The quality of the supply voltage should be to the standard of a typical business or hospital environment.
Surges in accordance with IEC	±1 kV conductor-conductor	±1 kV normal mode voltage	The quality of the supply voltage should be to the standard of a typical business or hos-

61000-4-5			pital environment.
Voltage dips, short interruptions and voltage variations on power supply in accordance with IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 1/2 period	<5% U_T (>95% dip in U_T) for 1/2 period	The quality of the supply voltage should be to the standard of a typical business or hospital environment. If the user of the BPM1401 blood pressure monitor requires continued operation during power mains interruptions, it is recommended that the BPM1401 blood pressure monitor is powered from an uninterruptible power supply or a battery.
	40% U_T (60% dip in U_T) for 5 cycles	40% U_T (60% dip in U_T) for 5 cycles	
	70% U_T (30% dip in U_T) for 25 cycles	70% U_T (30% dip in U_T) for 25 cycles	
	<5% U_T (>95% dip in U_T) for 5 s	<5% U_T (>95% dip in U_T) for 5 s	
Power frequency (50/60 Hz) magnetic field in accordance with IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTES: U_T is the AC mains voltage prior to application of the test level.			

MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY (IEC 60601-1-2)			
The BPM1401 blood pressure monitor is intended to be operated in the electromagnetic environment specified below. The customer or the user of the BPM1401 blood pressure monitor should ensure that it is operated in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment (EME) – guidance
Immunity to conducted disturbances induced by radio-frequency fields in accordance with IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the BPM1401 blood pressure monitor, including cables, than the recommended separation distance calculated from the equation appropriate to the frequency of the transmitter. **Recommended separation distance:** d = 1.167 $\sqrt{P}$
Radiated, radio-frequency, electromagnetic field immunity in accordance with IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	d = 1.167 $\sqrt{P}$ for 80 MHz to 800 MHz d = 2.333 $\sqrt{P}$ for 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters as determined by an electromagnetic site survey[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1	At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2	This guidance may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/ cordless) telephones and land mobile radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the BPM1401 blood pressure monitor is used exceeds the applicable RF compliance level above, the BPM1401 blood pressure monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the BPM1401 blood pressure monitor.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distance between portable and mobile RF communications equipment and the ME device or ME system – for ME devices or ME system that are not life-sustaining – are as follows:

RECOMMENDED SEPARATION DISTANCE BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE BPM1401 BLOOD PRESSURE MONITOR.

The BPM1401 blood pressure monitor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customers or the users of the BPM1401 blood pressure monitor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the BPM1401 blood pressure monitor as recommended below, according to the maximum output power of the communications equipment.

Output power of transmitter in Watts (W)	Separation distance according to frequency of the transmitter in metres (m)		
	150 kHz to 80 MHz $d = 1.167\sqrt{P}$	80 MHz to 800 MHz $d = 1.167\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.333\sqrt{P}$
0.01	0.167	0.167	0.233
0.1	0.369	0.369	0.738
1	1.167	1.167	2.333
10	3.690	3.690	7.338
100	11.67	11.67	23.33

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1	At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2	This guidance may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Guarantee card – 3 years on the blood pressure monitor (except wearing parts and batteries)

• Sender

• Reason for claim

• Date of purchase _____

Please return this section and proof of purchase to your retailer.

Operating Manual_BA1400_EN_131217_REV001

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